DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Re: Cook GRII™ Coronary Stent
Docket No.: 97E-0461

JUL 24 1998

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, DC 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 5,041,126, filed by Cook Incorporated, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Cook GRII™ Coronary Stent, the medical device claimed by the patent.

The total length of the regulatory review period for Cook GRII™ Coronary Stent is 511 days. Of this time, 343 days occurred during the testing phase and 168 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date a clinical investigation on humans involving this device was begun: December 20, 1995.

   FDA has verified the applicant's claim that the date the Investigational Device Exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act for human tests to begin became effective on December 20, 1995.

2. The date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act: November 26, 1996.

   The applicant claims November 23, 1996, as the date the Premarket Approval Application (PMA) Cook GRII™ Coronary Stent] (NDA 910030) was initially submitted. However, FDA records indicate that PMA 910030 was submitted on November 26, 1996.

3. The date the application was approved: May 12, 1997.

   FDA has verified the applicant's claim that PMA 910030 was approved on May 12, 1997.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Thomas J. McGinnis, R.Ph.
Deputy Associate Commissioner
for Health Affairs

cc: C. David Emhardt
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